K091505
p1/6

JUN 10 2009

510(k) Summary

GENERAL INFORMATION

5.1 Type of Submission

Traditional 510(k) Submission

Submission date: 04/21/2009

5.2 Submitter

Name: Cardinal Health Germany 234 GmbH

Address: Leibnizstrasse 7
D-97204 Hoechberg
Germany

Contact person in Germany:

Thomas Rust
Address: Cardinal Health Germany 234 GmbH
Leibnizstrasse 7, 97204 Hoechberg
Germany
Phone: +49 931 49 72 - 383
FAX: +49 931 49 72 - 62383
E-mail Thomas.Rust@cardinalhealth.com

Contact person in the U.S.:
(Official Correspondent)

Thomas Gutierrez
Address Cardinal Health 207 INC
22745 Savi Ranch Parkway
Yorba Linda, CA 92887
Phone/Fax: 714-283-8472
E-mail Thomas.Gutierrez@cardinalhealth.com

K091505
#2/6

5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Recorder, Magnetic Tape, Medical
(CFR 870.2800, Product Code DSH)

5.5 Trade Name

Cor12+

5.6 Device Classification

This is a Class II device

5.7 Classification Panel

74 Cardiovascular Part 870
Code DSH

5.8 Reason for Premarket Notification

New Device

5.9 Legally predicate marketed device

1.	H12+ Holter Recorder	K050896	Code DSH
2.	Cardiette Microtel ECG	K082124	Code DPS
3.	MasterScope ECG	K082539	Code BTY / DPS

5.10 Predicate Device Company

1. Mortara Instrument, INC.
2. Et Medical devices SpA
3. Cardinal Health Germany 234 GmbH

5.11 Device Description

The digital Holter ECG recorder Cor12+ is a portable battery operated ECG amplifier with build in data storage on memory card (Mini SD size):

- Single dual color (green/yellow) LED
- Button control (one Button) to activate communication interface, event recording
- Two standard size AA batteries
- Speaker for voice output for alarm messages
- PC program to set-up recorder via blue-tooth communication interface

5.12 Intended Use Statement

The Cor12+ Holter Recorder is intended to acquire, record and store ECG data of patients that have been connected to the Cor12+ recorder and are undergoing Holter monitoring. The Cor12+ acquires, digitizes and stores data to be analyzed on a computer with special software.

The Cor12+ is indicated for use:

in a clinical setting, by qualified medical professionals only, for recording ECG data of symptomatic patients requiring ambulatory (Holter) monitoring of up to 24 hours.
The Cor12+ performs no cardiac analysis by itself; it solely records the ECG signals. The patient population for this device is from 4 years on and a minimum weight of 10 kg.

5.13 Required Components

Cor12+ recorder
Accessories
User Manual

5.14 Summary Table of Comparison

a) Comparison of Cor12+ with H12+ (complete device functions)

	H12+ Holter Recorder (K050896)	Cor12+ Holter Recorder
Indications for Use	The H12+ Holter recorder is intended to acquire, record and store ECG data of patients that have been connected to the Mortara H12+ recorder and are undergoing Holter monitoring. The H12+ acquires, digitizes and stores data to be analyzed by the H-Scribe Holter system. The H12+ is indicated for use: - in a clinical setting, by qualified medical professionals only, for recording ECG data of symptomatic patients requiring ambulatory (Holter) monitoring of up to 48 hours. - the H12+ performs no cardiac analysis by itself and is intended to be used with the H-Scribe Holter analysis system (K004017). ECG data prerecorded by the H12+ is acquired and analyzed by the H-Scribe.	The Cor12+ Holter Recorder is intended to acquire, record and store ECG data of patients that have been connected to the Cor12+ recorder and are undergoing Holter monitoring. The Cor12+ acquires, digitizes and stores data to be analyzed on a computer with special software. The Cor12+ is indicated for use: - in a clinical setting, by qualified medical professionals only, for recording ECG data of patients requiring ambulatory (Holter) monitoring of up to 24 hours. The Cor12+ performs no cardiac analysis by itself; it solely records the ECG signals. The patient population for this device is from 4 years on and a minimum weight of 10 kg.
Patient population	The H12+ Holter Recorder can be used for patients from 4 years on and older.	The Cor12+ Holter Recorder can be used for patients from 4 years on and older. Minimum weight of 10 kg.
Dimensions (housing)	Length x Width x Height: 112*82*34 mm	Length x Width x Height: 100*70*26 mm

5 510(k) Summary

	Weight: 145 g (batteries included)	Weight: 155 g (batteries included)
Display	LCD module Size: 46,0 x 18,4 mm 100 x 32 dots	Dual color LED
Key-panel	Foil Key-panel (4 keys): - ESC (on/off) - UP-ARROW - DOWN-ARROW - OK	Single button: - Activate communication
Housing	Material: Rotec ABS 1001FR V0	Material: PC/ABS Cycoloy C1200
Input dynamic range	+/- 300mV @ DC	+/- 1300mV @ DC
Frequency response / Bandwith	0,05 -150 Hz According to EC11 and IEC 60601-1	**identical**
A/D conversion	20 bit	24 bit
Sampling rate for data storage	1000 Hz or 180 Hz	1000 Hz or 250 Hz
Leads	12 Standard – US color coding	**identical**
Interface	Compact Flash Memory Card (data storage and programming)	SD Memory Card (data storage) Bluetooth (programming)
Energy type	1 x 1,5 V (AA size)	2 x 1,5 V (AA size, Lithium)
Operating Require-ments	Programming Software	**Identical**
Mode of operation	Manual, Manual delayed and Automatic recording	Automatic recording

5 510(k) Summary

b) Comparison of Cor12+ with Cardiette Microtel ECG Recorder (communication interfaces)

	Cardiette Microtel (K082124)	Cor12+ Holter Recorder
Interface	Bluetooth & USB	Bluetooth & SD-Card

c) Comparison of Cor12+ with MasterScope ECG (electrode impedance)

	MasterScope ECG (K082539)	Cor12+ Holter Recorder
Electrode impedance	Impedance measurement for electrode	**Identical**

Discussion to the device differences of the table a), b) and c) above.

The significant differences to the H12+ ECG Recorder are found as:

- **No display** – The main purpose of the display on the H12+ recorder is the programming of the device (set of time, subject ID, etc.). In the Cor12+ this programming of the device is performed by a PC program and direct blue-tooth communication. Therefore no display is needed on the Cor12+ to allow its intended use
- **Input Dynamic Range** – The Cor12+ has a better input range compared with the predicate device. This allows the recording of the ECG even with increased baseline drift.
- **Sampling Rate** – The lower sampling rate (250 Hz) for data storage is slightly higher compared with the predicate device H12+ (160 Hz). This slightly higher frequency is beneficial for the accuracy and resolution of further data processing.
- **Bluetooth** - is used for programming the Cor12+ instead programming by keypad/display and memory-card as it is with the H12+ device. The Bluetooth is not for data transfer of measurement data, it is only for the purpose to program the Cor12+ for the patient. The measurement data are transferred to the computer by memory-card as it is provided also by the predicate device H12+.

The community to the Cardiette Microtel ECG Recorder is found as:

- **Interface Bluetooth** – Common is that both devices work with a Bluetooth interface, whereas the Cor12+ uses the Bluetooth interface only to program the patient device and not to transfer the measurement data.

The community to the MasterScope ECG is found as:

- **Electrode impedance** – Common is that both devices work with electrod impedance measurement. Electrode contact quality is determined by measuring the impedance at each electrode. If impedance is below a certain value, electrode contact is good and the green LED lights up. For impedance values above this value, the electrode contact is not sufficient to guarantee good ECG quality. The red LED on the corresponding electrode clip lights up. This feature enables easy and straightforward check of electrode contact quality.

5.15 Summary of Device Testing

The following practices were followed and monitored for development of the Holter ECG recorder Cor12+:

- The Cor12+ was developed in accordance with the Cardinal Health development standard operating procedures (000490 06 – Design Control).
- The risk analysis method used to assess the impact of Cor12+ was a Failure Modes and Effects Analysis (FMEA).
- Safety test procedures demonstrate satisfaction of all safety requirements and mitigation of all identified hazards.
- The EMC testing was performed according EN 60601-1-2 and EN 60601-2-47.
- Electrical Safety.testing was performed according IEC 60601-1 and IEC 60601-2-47.

5.16 Conclusions

Based on the above, Cardinal Health Germany 234 GmbH concludes that the Cor12+ is substantially equivalent to legally marketed predicate device "H12+" and the two options Bluetooth and Electrode impedance are equivalent to the devices "Cardiette Microtel" and "MasterScope ECG". The Cor12+ is safe and effective for its intended use, and performs at least as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 2009

Cardinal Health 207, Inc.
c/o Mr. Thomas Gutierrez
22745 Savi Ranch Parkway
Yorba Linda, CA 92887

Re: K091505
Cor12+
Regulation Number: 21 CFR 870. 2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: DSH
Dated: May 15, 2009
Received: May 21, 2009

Dear Mr. Gutierez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091505

Indications for Use

510(k) Number (if known): K

Device Name: Cor12+

Indications for Use:

The Cor12+ Holter Recorder is intended to acquire, record and store ECG data of patients that have been connected to the Cor12+ recorder and are undergoing Holter monitoring. The Cor12+ acquires, digitizes and stores data to be analyzed on a computer with special software.

The Cor12+ is indicated for use:
in a clinical setting, by qualified medical professionals only, for recording ECG data of symptomatic patients requiring ambulatory (Holter) monitoring of up to 24 hours.

The Cor12+ performs no cardiac analysis by itself; it solely records the ECG signals.
The patient population for this device is from 4 years on and a minimum weight of 10 kg.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Fuckerman

(Division Sign-Off) 6/10/09
Division of Cardiovascular Devices

510(k) Number K091505